JONES DAY | **Food, Dietary Supplement & Cosmetics Regulatory Update**
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Top News

FDA Issues Three Major FSMA Final Rules
On November 13, 2015, FDA published three major Food Safety Modernization Act ("FSMA") rules. These final rules require food importers and producers to undertake systemic safety measures designed to prevent outbreaks of foodborne illness. The three rules are:

1. Foreign Supplier Verification Programs ("FSVP"). Requires importers to verify that food imported into the U.S. has been produced in a manner consistent with U.S. safety standards. Imported food accounts for about 19 percent of the U.S. food supply, including about 52 percent of fresh fruits and 22 percent of fresh vegetables.

2. Accredited Third-Party Certification. Establishes a program for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications of foreign food facilities and the foods they produce.

3. Produce Safety. Establishes science-based standards that must be adopted by foreign and domestic farms growing, harvesting, packing, or holding fresh fruits and vegetables for human consumption.

These final rules build on the preventive controls rules the FDA published in September 2015 (see our previous *Update*), mandating modern preventive practices in food processing and storage facilities. For more information regarding these three rules, please see our recent *Alert*.

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RELATED PRACTICES

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FDA Issues Guidance on Voluntary Labeling of Genetically Engineered Foods
On November 24, 2015, FDA issued a final guidance indicating that manufacturers can voluntarily decide whether to label their foods as having been or not having been derived from genetically engineered ("GE") plants. FDA does not *require* GE foods to be labeled as such, and it states that it is not aware of "any information showing that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding." On the other hand, FDA states manufacturers may voluntarily label their foods with information about whether the foods were not produced using bioengineering, as long as such information is truthful and not misleading. In addition, the guidance states FDA's preference for the use of the term "genetic engineering" as opposed to "genetic modification" or "genetic modified organisms (GMOs)," and recommends not using "GMO free" or similar claims due to the potential challenges of substantiating a "free" claim.

At the same time, FDA approved the sale of GE AquAdvantage Salmon, representing the first time the agency approved the sale of a GE animal product for public consumption. The salmon is engineered to grow faster, but not larger, than the naturally occurring variety. In support of the New Animal Drug Application related to AquAdvantage Salmon, the agency conducted an Environmental Assessment ("EA") and made a Finding of No Significant Impact ("FONSI") on the human environment. The EA and FONSI were issued under certain commitments, such as limiting where the salmon could be grown or the physical containment conditions used, among others.

FDA Issues Proposed Rule Titled "Gluten-Free Labeling of Fermented or Hydrolyzed Foods"
On November 17, 2015, FDA announced a proposed rule to establish requirements for fermented and hydrolyzed foods bearing the gluten-free label, such as yogurt, sauerkraut, pickles, cheese, green olives, vinegar, and FDA-regulated beers. The rule, if implemented, would require manufacturers of these products to keep records showing that: (i) the products meet the gluten-free label requirements prior to fermentation or hydrolysis, (ii) any potential gluten cross-contact has been evaluated, and (iii) when a cross-contact potential has been identified, measures have been implemented to prevent the introduction of gluten into the food. The FDA has issued this proposed rule to provide alternative means for the agency to verify compliance of these products with the FDA gluten-free labeling final rule of 2013. For more information, see our previous *Update*.

FDA Issues Four Draft Guidance Documents Related to Over-the-Counter Sunscreens
On November 20, 2015, FDA released four guidance documents regarding the Time and Extent Application ("TEA") process followed to request a new Over-the-Counter ("OTC") drug monograph for sunscreens or amend an existing monograph to recognize that a sunscreen active ingredient or condition is Generally Recognized as Safe and Effective ("GRASE"). FDA is issuing these guidance documents to meet the one-year deadline imposed by the Sunscreen Innovation Act ("SIA") upon its enactment in 2014. The four published documents aim to provide information on: (i) the safety and effectiveness data needed for submission to determine whether a nonprescription sunscreen active ingredient or combination of active ingredients is GRASE, (ii) the content and format of data submission to support a GRASE determination, (iii) the consequences and process of withdrawing a sunscreen TEA request or pending request, and (iv) the conditions under which an advisory committee review should be requested. As mentioned below in the "Regulatory Updates" section, comments must be submitted by January 22, 2016.

A New Cosmetic Bill Is Introduced in Congress
On November 18, 2015, Representative Peter Sessions introduced the Cosmetic Modernization Amendments of 2015 (H.R. 4075) to amend certain provisions of the Federal Food, Drug and Cosmetic Act ("FD&C Act"). This bill would amend the current

definition for "cosmetics," allowing some of the products that are currently considered drugs to fall under the updated cosmetics definition, which states that "an article … that is intended only for topical external use to alter the appearance by temporarily affecting the structure or any function of the human skin, and that is not the subject of an approved new drug application under section 505, shall, for purposes of this Act, be treated only as a cosmetic and not a drug." This bill is a similar version of previously introduced bills such as the Safe Cosmetics Act of 2010 (H.R. 5786), the Cosmetic Safety Amendments Act of 2012 (H.R. 4395), the Safe Cosmetics and Personal Care Products Act of 2013 (H.R. 1385), the Humane Cosmetics Act of 2014 (H.R.4148), and the more recent Personal Care Products Safety Act of 2015 (S. 1014) (see our previous *Update).*

EPA Issues Final Cancellation Order for Pesticide Products Containing Sulfoxaflor
On November 12, 2015, the Environmental Protection Agency ("EPA") issued a final cancellation order prohibiting the sale and distribution of all pesticide products containing the active ingredient sulfoxaflor. The EPA approval of sulfoxaflor as a pesticide was sought by and granted to Dow AgroSciences in 2010. However, the honey beekeeping industry filed a lawsuit against the EPA in 2013, challenging approval of this ingredient on the grounds that its use negatively affected bee populations. On September 10, 2015, the U.S. Court of Appeals for the Ninth Circuit vacated sulfoxaflor's registration, stating that EPA relied on "flawed and limited data" to approve the registration of sulfoxaflor, and thus the approval was not supported by "substantial evidence."

EFSA Provides Guidance on Foods for Special Medical Purposes
On November 26, 2015, the European Food Safety Authority ("EFSA") published a guidance document, Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No. 609/2013. Foods for Special Medical Purposes ("FSMPs") are designed to feed patients who have a limited, impaired, or disturbed capacity to take, digest, absorb, metabolize, or excrete ordinary foods, or certain nutrients or metabolites, or who have specific medical nutrient requirements, typical to a disease/disorder/medical condition, that cannot be reasonably or realistically satisfied by modifying the normal diet. Regulation No. 609/2013 applies to FSMPs, as well as infant formula and follow-on formulae, processed cereal-based foods and baby foods, and total diet replacements for weight control. It repeals and replaces the existing framework legislation on products previously known as "foods for particular nutritional uses" and will come into effect in July 2016. The guidance presented in this document is aimed at assisting in the preparation and presentation of well-structured dossiers by establishing: (i) a common format for the organization of the information, (ii) the information and scientific data that could be included in the dossier, and (iii) the key issues that should be addressed in the dossier.

The European Commission Publishes Roadmap on Use of Bisphenol A in Food Contact Materials
On November 20, 2015, the European Commission's Directorate-General for Health and Food Safety ("DG SANTE") published a Roadmap for a new measure on bisphenol A ("BPA") in food contact materials ("FCMs"), such as plastic (polycarbonates) and coatings (epoxy resins). Its use in FCMs is approved, and it is only banned for polycarbonate infant feeding bottles. Following uncertainties surrounding potential health effects, EFSA conducted a re-evaluation of the risks to human health associated with exposure to BPA and concluded in January 2015 that "BPA poses no health risk to consumers of any age group (including unborn children, infants and adolescents) at current exposure levels." See our previous *Update*. However, EFSA's scientific opinion considerably reduced the "tolerable daily intake" or "TDI" from 50 micrograms per kilogram of body weight per day (µg/kg of bw/day) to 4 µg/kg of bw/day.

Furthermore, since January 2015, the presence of BPA in any type of FCM is banned in France, and other Member States have introduced measures to reduce the presence of BPA in FCMs for children. In response to the EFSA re-evaluation and to the emergence of diverging national rules concerning the use of BPA, the Roadmap presents and assesses the following five options for harmonizing the use of BPA in FCMs: (i) no policy change,

(ii) modification of legislative restrictions for BPA only in plastic FCMs at EU level, (iii) modification of legislative restrictions for BPA in plastic FCMs at EU level and introduction of measures for BPA in coatings and varnishes at EU level, (iv) modification of legislative restrictions for BPA in plastic FCMs at EU level and introduction of measures for BPA in food contact coatings and varnishes as well as other food contact materials in which BPA may be present, and (v) ban on BPA in all FCMs at EU level. No time frame is specified for an implementation plan; however, DG SANTE plans to discuss next steps with "all relevant stakeholders including EU Member States and industry." The Roadmap is open for public consultation until December 17, 2015.

Other News
Former U.S. Agriculture Secretaries Urge Congress's TPP Passage

FDA Announces New Web Resource on Sampling for Food Safety

FDA and DOJ File Criminal Charges Against USPlabs for Fraudulently Manufacturing and Selling Dietary Supplements

Suit Challenging FDA Approval of Ractopamine-Based Products for Livestock Dismissed

USDA Clears Chicken and Turkey Farms Infected by Avian Influenza to Restock their Flocks

EU Concludes Use of Glyphosate as Herbicide is "Unlikely" to Cause Cancer

Bird Flu Outbreak Discovered in France

Regulatory Updates

FDA Issues Final Rule Regarding Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
As discussed above, in the November 27, 2015, *Federal Register*, FDA adopted a regulation on foreign supplier verification programs ("FSVPs") for importers of food for humans and animals. The regulation requires importers to verify that food they import into the United States is: (i) produced in compliance with the hazard analysis and risk-based preventive controls and standards for produce safety provisions of the FD&C Act, (ii) not adulterated, and (iii) not misbranded with respect to food allergen labeling. ***Final rule is effective January 26, 2016. Compliance date for this rule is May 27, 2017***.

FDA Issues Final Rule Regarding Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications
As discussed above, in the November 27, 2015, *Federal Register*, FDA adopted regulations to provide for accreditation of third-party certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications, under the FSMA. These certifications will be required for participation in the voluntary qualified importer program established under the FD&C Act. In addition, when the Agency has determined that an imported food is subject to certification under FSMA, the Agency may require a certification under this rule as a condition for admitting the food into the United States. ***Final rule is effective January 26, 2016. FDA intends to implement this program as soon as possible***.

FDA Issues Final Rule Regarding Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
As discussed above, in the November 27, 2015, *Federal Register*, FDA published a final rule establishing science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA established these standards as part of its implementation of the FSMA. These standards do not apply to produce that is rarely consumed raw, produce for

personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this rule. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. In addition, FDA has made available for public review the Final Environmental Impact Statement and Record of Decision for these standards. ***Final rule is effective January 26, 2016. Compliance date for this rule is November 27, 2017, with later compliance dates for small and very small farms***.

FDA Clarifies Compliance Date for Certain Facilities Subject to Final Rule "Preventive Controls for Human Food"
In the November 18, 2015, *Federal Register*, FDA clarified the compliance date provided for certain food establishments subject to the "Preventive Controls for Human Food" final rule, published on September 17, 2015. The Agency took this action in response to requests for clarification of the compliance date for facilities that manufacture, process, pack, or hold grade "A" milk or milk products, and that are regulated under the National Conference on Interstate Milk Shipments ("NCIMS") system. The Agency clarified that the extended compliance date of September 17, 2018, for Pasteurized Milk Ordinance ("PMO") facilities applies only to grade "A" milk and milk products covered by NCIMS under the PMO, and not to the manufacturing, processing, packing, or holding of other food.

FDA Issues Two Guidance Documents Titled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants" and "Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon"
As discussed above, in the November 24, 2015, *Federal Register,* see here and here, FDA announced the availability of two guidance documents for industry titled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants," and "Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon." Both guidance documents are intended to help food manufacturers wishing to voluntarily label plant-derived food products or ingredients (for humans or for animals), or food product or ingredients (for humans or animals) derived from Atlantic salmon, as having been made with or without bioengineering. ***Comments are due December 24, 2015***.

FDA Proposes Rule to Establish Additional Requirements on "Gluten-Free" Labeling for Certain Foods
As discussed above, in the November 18, 2015, *Federal Register*, FDA proposed to establish additional requirements concerning "gluten-free" labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to foods labeled as "gluten-free." ***Comments are due February 16, 2016***.

FDA Issues Guidance Titled "Over-the-Counter Sunscreens: Safety and Effectiveness Data"
As discussed above, in the November 23, 2015, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Over-the-Counter Sunscreens: Safety and Effectiveness Data." This draft guidance addresses FDA's current thinking about the safety and effectiveness data needed to determine whether a nonprescription sunscreen active ingredient or combination of active ingredients evaluated under the SIA is GRASE and not misbranded when used under specified conditions. The guidance also addresses FDA's current thinking about an approach to safety-related final formulation testing that it anticipates adopting in the future. ***Comments are due January 22, 2016***.

FDA Issues Guidance Titled "Nonprescription Sunscreen Drug Products—Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act"
As discussed above, in the November 23, 2015, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Nonprescription Sunscreen Drug Products—Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act." This draft guidance addresses FDA's current thinking on how it will determine whether a sponsor's submission of safety and efficacy data is sufficiently complete to support a substantive review and determination under the SIA that an active ingredient is or is not GRASE for use in nonprescription sunscreen products. ***Comments are due January 22, 2016***.

FDA Issues Guidance Titled "Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request"
As discussed above, in the November 23, 2015, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Sunscreen Innovation Act: Withdrawal of a 586A Request or Pending Request." This draft guidance provides recommendations for the process for withdrawing a 586A request submitted under the FD&C Act, as amended by the SIA, and withdrawing a pending request, as defined by the SIA. This guidance applies to requests that seek a determination from FDA of whether a nonprescription sunscreen active ingredient, or a combination of nonprescription sunscreen active ingredients, is GRASE for use under specified conditions and should be included in the OTC sunscreen drug monograph. ***Comments are due January 22, 2016***.

FDA Issues Guidance Titled "Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process"
As discussed above, in the November 23, 2015, *Federal Register*, FDA announced the availability of a draft guidance for industry titled "Sunscreen Innovation Act: Section 586C(c) Advisory Committee Process." This draft guidance explains the process by which FDA intends to carry out the section of the FD&C Act, as amended by the SIA, that governs the convening of advisory committees and the number of requests to be considered per meeting. The recommendations in this draft guidance apply to: (i) 586A requests submitted under the FD&C Act, and (ii) pending requests that seek a determination from FDA on whether a nonprescription sunscreen active ingredient, or a combination of nonprescription sunscreen active ingredients, is GRASE for use under specified conditions and should be included in the OTC sunscreen drug monograph. ***Comments are due January 22, 2016***.

FDA Announces Food Additive Petition for Safe Use of Sodium Formate
In the November 24, 2015, *Federal Register*, FDA announced that BASF Corp. filed a petition on October 15, 2015 proposing that the food additive regulations be amended to provide for the safe use of sodium formate as a feed acidifier in poultry feed.

FSIS Issues Updated Compliance Guidelines for Allergens and Ingredients of Public Health Concern
In the November 16, 2015, *Federal Register*, USDA's Food Safety and Inspection Service ("FSIS") issued an updated version of the Agency's compliance guidelines for controlling hazards posed by allergens and other ingredients of public health concern. The guidelines provide recommendations for identifying hazards when conducting a hazard analysis and for preventing and controlling hazards through a hazard analysis and critical control point plan, or sanitation standard operating procedures, or other prerequisite programs with respect to these substances.

APHIS Reopens Comment Period on Scrapie Regulations
In the November 16, 2015, *Federal Register*, USDA's Animal and Plant Health Inspection Service ("APHIS") reopened the comment period for a proposed rule that would revise completely the scrapie regulations that concern: (i) the risk groups and categories established for individual animals and flocks, (ii) the use of genetic testing as a means of assigning risk levels to animals, (iii) movement restrictions for animals found to be

genetically less susceptible or resistant to scrapie, and (iv) recordkeeping requirements. ***Comments are due December 9, 2015***.

USDA Appoints Performance Review Board
In the November 10, 2015, *Federal Register*, USDA's Office of Human Resource Management, announced the appointment of members of the USDA's Senior Executive Service, Senior Level, and Scientific or Professional Performance Review Boards ("PRB"). USDA has a total of six PRBs: (i) the Secretary's PRB, (ii) the Departmental Management and Staff Offices PRB, (iii) the Natural Resources and Environment PRB, (iv) the Farm and Foreign Agricultural Services, Rural Development, and Food, Nutrition, and Consumer Services PRB, (v) the Marketing and Regulatory Programs, Food Safety PRB, and (vi) the Research, Education, and Economics PRB. The boards meet annually to review and evaluate performance appraisal documents and provide written recommendations of executives to the Secretary for final approval of performance ratings and base salary increases. ***Appointments are Effective November 2, 2015***.

Federal Crop Insurance Corporation Amends Area Risk Protection Insurance Regulations
In the November 25, 2015, *Federal Register*, the Federal Crop Insurance Corporation ("FCIC") issued a final rule amending the Area Risk Protection Insurance ("ARPI") Regulations to meet the goals of the USDA's Acreage Crop Reporting Streamlining Initiative. This would align ARPI Forage Production with the Actual Production History Forage Production Crop Insurance Provisions and would address language contained in section 12305(b)(1)(B) of the 2014 Farm Bill prohibiting FCIC from offering the catastrophic level coverage for any crops or grasses used for grazing. The changes will be effective for the 2017 and succeeding crop years. ***Rule is effective November 25, 2015, and comments are due January 25, 2016***.

Other USDA Announcements:
- AMS Decreases Assessment Rate of Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas
- APHIS Issues Final Rule to Remove Manhattan, Staten Island, Suffolk, and Norfolk from List of Quarantine Areas for Asian Longhorned Beetle
- AMS Increases Assessment Rate of Onions Grown in South Texas
- AMS Increases Assessment Rate of Raisins Produced from Grapes Grown in California
- AMS Decreases Assessment Rate of Tomatoes Grown in Florida

USDA Announced the Following Requests for Information:
- Deferment of RUS Loan Payments for Rural Development Projects
- Erroneous Payments in Child Care Centers Study
- 7 CFR part 210, National School Lunch Program
- Generic Clearance for the Special Nutrition Programs Quick Response Surveys
- Review of Supplemental Nutrition Assistance Program/Medicaid Eligibility Technology Integration
- Uniform Grant Application Package for Discretionary Grant Programs
- Federal Claims Collection Methods for Supplemental Nutrition Assistance Program Recipient Claims

USDA Announced the Following Proposed Information Collections:
- National Agricultural Statistics Service to Gather Data Related to the Production and Marketing of Foods Directly from Farm Producers to Consumers or Retailers

USDA Announced the Following Information Collections Have Been Revised and/or Extended:
- Agriculture Innovation Centers
- Select Agent Registration

USDA Announced the Following Information Collections Have Been Submitted to OMB:

- Evaluation of Supplemental Nutrition Assistance Program Employment and Training Pilots
- Measurement Service Records
- Generic Clearance for Survey Research Studies

FDA Announced the Opportunity to Comment on the Following Proposed Information Collections:

- Dietary Supplement Labeling Requirements and Recommendations Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Use of the FDA Electronic Submission Gateway and the Safety Reporting Portal to Collect Adverse Event Reports and Other Safety Information for FDA-Regulated Products

FDA Announced the Following Information Collections Have Been Submitted to OMB:

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food

European Regulatory Updates

EFSA Publishes List of Upcoming Consultations
An overview of the public consultations EFSA has planned for the coming months is now available on the EFSA website. Upcoming consultations include a public consultation on the draft Guidelines regarding a possible derogation of existing requirements for applications of genetically modified food and feed at low levels submitted under Regulation (EC) No 1829/2003, and public consultations on dietary reference values.

Upcoming Meetings, Workshops, and Conferences

Food Advisory Committee, **December 7–8, 2015**, in Silver Spring, MD.

Public Meeting of the Council for Native American Farming and Ranching Advisory Committee, **December 8–9, 2015**, in Las Vegas, NV.

Public Meeting of the Advisory Committee on Biotechnology and 21st Century Agriculture ("AC21"), **December 14–15, 2015**, in Washington, D.C.

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